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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
12/16/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/591,604	DAIMON ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 11-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/1/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III (method claims 7-10) in the reply filed on 5/18/10 is acknowledged. The traversal is on the ground(s) that "[r]estriction is only proper if the claims of the restricted are independent or patentably distinct and there would been serious burden placed on the Examiner if restriction is not required". This is not found persuasive because of the reasons made of record in Paper No: 20070924, and importantly because no "special" technical feature still exists for Group I, as illustrated by the Rosenfield reference/ "example" made of record in the restriction requirement of Paper No: 20100312, and the rejection under 35 U.S.C. 102 below, in this 371 application. Therefore, no unity of invention exists, because the claimed invention did not provide a contribution over the prior art, and because PCT Rule 13 does not provide for multiple products or methods within a single application, especially when the technical feature of the Group I invention is not a "special" technical feature. Moreover, mixing and matching different sections of the MPEP not concerning practice under PCT Rule 13 does not constitute a proper argument; especially when applicant has not made the argument that each and every distinct invention is obvious over the elected invention, or the nonelected invention of Group I.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-6 & 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/23/07.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification states that "[a] commercially available product can be used as the anti-BDNF monoclonal antibody" on page 13 of the specification, and then generically describes how an anti-BDNF can be obtained on pages 15-16 of the specification. Although it could be argued that human BDNF molecule is structurally well known in the art, which was isolated by Barde et al. in 1982, and that antibodies against this human BDNF molecule were also known in the art, the claims are not directed to any structurally known species of anti-BDNF antibodies. In contrast, the claim language of "a" brain-derived neurotrophic factor implies a genus of multiple BDNF molecules, which have not been described within the instant specification, and their corresponding anti-BDNF antibodies, which have not been described within the instant specification.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered

include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. Therefore, in the absence of sufficient recitation of distinguishing identifying characteristics, because one skilled in the art cannot structurally visualized any other anti-BDNF antibody, except for possibly an anti-human BDNF antibody, because none others are described, and because the specification does not reasonably show possession of the genius of anti-BDNF antibodies for use in the currently claimed method, in order for one to reasonably visualize how to assay for "an ischemic heart disease risk group", as currently claimed, the written description requirements under 35 U.S.C. 112, first paragraph, are not met. See MPEP 2163.

Accordingly, Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, 1117, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the claimed invention". "The invention is, for purposes of the 'written description' inquiry, whatever is now claimed [emphasis added]".

3. Claims 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the current methods are incomplete in not reciting how and when one knows they have completed the invention, as recited in the preamble, such as when "measuring a brain-derived neurotrophic factor concentration" alone constitutes "an assay method for an ischemic heart disease risk group". For example, it is unknown what constitutes a "risk group"

versus some unrecited control group, in that no comparison claim language is recited, and in which it is unclear what a corresponding increase or decrease in BDNF levels would mean, if eventually measured (and recited), versus measuring some unknown BDNF "concentration" by itself.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Chaldakov et al (2001; IDS Ref #AX).

Chaldakov et al teach an assay method comprising measuring BDNF in the blood of patients with "extreme high risk for myocardial infarction" characterized as having metabolic syndrome (see Abstract; pg. 358). In particular, 23 patients with metabolic syndrome blood samples were collected and BDNF levels were measured in an ELISA, which necessarily requires labeled anti-BDNF antibodies (i.e., as it relates to claim 9), and wherein measuring a lower level of BDNF (i.e., 7012 pg/ml vs. 8697 pg/ml) indicates metabolic syndrome when compared to control (pg. 358; 1st column & Table 1; as it relates to claims 7-8, 9 & 10).

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Stucker, can be reached on (571) 272-0911. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert C. Hayes/, Ph.D.
Primary Examiner, Art Unit 1649
December 9, 2010